

**STATE OF MICHIGAN**  
**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

**In the matter of**

**XXXXXX**

**Petitioner**

**v**

**File No. 121554-001**

**Priority Health**

**Respondent**

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**Issued and entered**  
**this 10<sup>th</sup> day of January 2012**  
**by R. Kevin Clinton**  
**Commissioner**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On September 14, 2011, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the information received, the Commissioner accepted the request for external review on September 22, 2011.

The Petitioner is a member of Priority Health, a health maintenance organization. Her coverage became effective on January 1, 2010. The Commissioner notified Priority Health of the external review and requested the information used in making its adverse determination. The Office of Financial and Insurance Regulation received the information on September 28, 2011.

The case involves medical issues. Pursuant to MCL 550.1911(6), the Commissioner assigned the matter to an independent review organization, which submitted its analysis on October 6, 2011. (A copy of the complete report is being provided to the parties with this Order.)

**II. FACTUAL BACKGROUND**

Petitioner has a history of gastroesophageal reflux disease (GERD), also known as acid reflux, for over 10 years for which she was taking Aciphex, a drug known as a proton pump inhibitor (PPI) to control her condition which has worked effectively.

From January 1, 2010 through March 31, 2011, Priority Health provided coverage for Aciphex. In March 2011, Priority Health advised Petitioner that effective April 1, 2011, it would no longer provide coverage for brand name PPIs such as Aciphex. Petitioner requested that Priority Health continue prescription drug coverage of Aciphex for the treatment of her condition. Priority Health denied the request for continued coverage.

Petitioner appealed the denial of continued coverage of Aciphex through Priority Health's internal grievance process. Priority Health maintained its denial and issued a final adverse determination dated August 18, 2011.

### **III. ISSUE**

Did Priority Health properly deny coverage for Aciphex?

### **IV. ANALYSIS**

#### Petitioner's Argument

In her request for external review, the Petitioner stated that she was aware that Priority Health had excluded coverage for Aciphex as early as January 1, 2010. However, Priority Health always made an exception to the rule and provided coverage for Aciphex. Petitioner also states she has tried and failed other proton pump inhibitors such as Prevacid, Zegerid OTC, Protonix and Prilosec. The Petitioner states she does not know why the other proton pump inhibitors do not work and neither does her physician.

The Petitioner believes Priority Health should provide coverage for the Aciphex because it is the only medication that significantly improves her acid reflux.

#### Respondent's Argument

In its final adverse determination of August 18, 2011, Priority Health denied coverage for the Aciphex stating:

As of April 1, 2011, brand name Aciphex will no longer be covered in accordance with the Priority Health Certificate of Coverage, Prescription Drug Rider, Pharmacy Policy 11/0024/R1 for Exclusion of coverage for specific prescription drugs, and Formulary for Aciphex.

In its position paper dated September 27, 2011, and submitted to the Commissioner for this review, Priority Health provided the following in explanation of its decision:

Priority Health's P & T Committee manages Priority Health's Drug Formulary by reviewing new and existing prescription drugs. The criteria for clinical decisions are based on scientific evidence and standards of practice, peer reviewed medical literature, well-established clinical practice guidelines, pharmacoeconomic studies, and therapeutic advantages with regards to safety and efficacy. The P & T Committee reviewed the class of brand-name proton pump inhibitors including Aciphex and determined that there is no data available which shows that brand-name proton pump inhibitors are superior to their over-the-counter generic equivalents in either outcomes or decreased adverse events. As a result, the P & T Committee concluded that brand name proton pump inhibitors including Aciphex would be removed from the formulary effective April 1, 2011.

Over the last decade, many pump inhibitors (PPIs) that were previously only available as brand-name drugs, have become increasingly available in generic-equivalent forms and many are currently available for purchase without a prescription (over-the-counter). Because of the widespread availability of generic-equivalent and over-the-counter PPIs that are considered to be equal in both safety and effectiveness to their brand name counterparts, Priority Health concluded that brand name PPIs including Aciphex would be removed from the formulary effective April 1, 2011.

It should be noted that Priority Health's formulary still includes coverage for generic-equivalent and over-the-counter PPIs including Prilosec OTC, Prevacid OTC, Zegrid OTC, omeprazole, lansoprazole, and pantoprazole. [Petitioner] notes previous trial and failure of over-the-counter equivalent drugs; however, Priority Health has reviewed [Petitioner's] drug history and determined that the dosages of the over-the-counter equivalent drugs that [Petitioner] tried were not equivalent to her prescribed dose of Aciphex. Based on the above facts, Priority Health denied coverage on behalf of [Petitioner] for brand name PPIs including Aciphex.

### Commissioner's Review

If an HMO provides prescription drug coverage, then it must comply with section 3406o of the Insurance Code, MCL 500.3406o. Section 3406o states in pertinent part:

An insurer that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:

\* \* \*

(c) Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or

another process for consideration of coverage or higher cost-sharing for nonformulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted.

Under Section 3406o, Priority Health has limited the Petitioner's pharmacy benefits "to drugs included in a formulary" and therefore it must provide an exception from that limitation if a nonformulary alternative is "medically necessary and appropriate." The question of whether Aciphex is a medically necessary and appropriate alternative for the Petitioner was presented to an independent review organization (IRO) for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with a subspecialty in gastroenterology. The IRO reviewer's report includes the following:

The enrollee has uncomplicated Gastroesophageal Reflux Disease (GERD). The recent endoscopy had a normal esophagus. There has been no documentation in the form of progress notes or pharmacy history substantiating the claim that multiple other PPIs have been tried and failed. It has not been substantiated by progress notes or pharmacy data, that the enrollee had adherent trials, intolerance or got sick from any other PPI agents. Since all PPIs are considered effective for GERD at proper dosing, the request for Aciphex specifically is not medically necessary.

The IRO reviewer concluded that Aciphex is not medically necessary for treatment of the Petitioner's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that Aciphex is not medically necessary for treatment for Petitioner's condition.

## **V. ORDER**

The Commissioner upholds Priority Health's final adverse determination of August 18, 2011. Priority Health is not responsible for providing prescription drug coverage for Aciphex.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton  
Commissioner